

## **Section II (Remarks)**

### **Concurrent Filing of RCE**

An RCE is concurrently filed herewith, as noted earlier herein.

### **Amendment of Claim 1 and Addition of New Claims 18-20**

Claim 1 has been amended herein to further specify the invention of such claim. After the recital of “dissolving a biodegradable polymer together with a polyoxyethylene-derived block copolymer in a nonpolar organic solvent” in claim 1, the phrase “to form a solution” has been inserted to provide appropriate antecedent basis for the subsequent recital of “the solution” in such claim.

Claim 1 has also been amended after the recital of “the solution obtained” to insert the words “in step a)” to make clear the antecedent basis.

The definite article “the” has been removed from preceding the recital of “aqueous phase” to resolve the antecedent basis issue of such recital.

Claim 1 has been further amended to recite “wherein the method does not involve a cholesterol compound,” consistent with the disclosure at page 6, line 35 to page 7, line 2 of the application, describing the deficiencies of U.S. Patent 5,962,566 (Grandfils et al) (“Nevertheless, this document indicates the incorporation of cholesterol as an essential ingredient for nanoparticle formation”).

New claims 18-20 have been added, with claim 18 reciting that the claimed method “consists essentially of” steps a) to d), and claim 19 reciting that the claimed method “consists of” steps a) to d). Claim 20 recites that the biodegradable polymer is a polyester or polyanhydride, the block

copolymer is a poloxamer, and the weight ratio of the biodegradable polymer to the polyoxyethylene-derived polymer is between 1:1 and 1:3, consistent with claims 3, 4, 6 and 11.

Accordingly, no new matter (35 USC 132) has been added by such amendment/addition of claims.

### **Patentable Distinction of Claims 1-20 Over the Cited References**

In the October 20, 2008 Office Action, claims 1-17 were rejected on reference grounds, including:

- a rejection of claims 1-3, 6-7 and 10-17 under 35 U.S.C. 102(b) as being anticipated by Grandfils et al. (US 5,962,566); and
- a rejection of claims 1-17 under 35 U.S.C. 103(a) as being unpatentable over Grandfils (US 5,962,566) in view of Levy et al. (WO 96/20698).

The now-pending claims 1-20 patentably differentiate from Grandfils for at least the reason that the claimed methodology of claim 1, which is required by all remaining claims 2-20, “does not involve a cholesterol compound.” By contrast, Grandfils requires a cholesterol compound (“a biocompatible cholesterol interacting agent” – see Abstract of Grandfils, line 5, and column 3, lines 34-37 of such reference). Accordingly, Grandfils cannot anticipate claim 1, or any of the claims 2-20 that either depend therefrom or otherwise require the methodology of such claim.

Concerning the combination of Grandfils in view of Levy, the hypothetical modification of Grandfils based on Levy does not alter the compositional requirement of Grandfils for a cholesterol compound. Since such a cholesterol compound is expressly excluded by amended claim 1 (see discussion, *supra*), claim 1 as well as claims 2-20 patentably delineate over Grandfils in view of Levy, for at least such reason.

The rejection of claims 1-17 is correspondingly traversed, in application to claims 1-20 as variously amended/added herein. It therefore is requested that the rejection of claims 1-17 on the stated grounds be withdrawn, and that a Notice of Allowance be issued for claims 1-20 now pending in the application.

**Fees Payable for Response**

The fees payable for this response include an RCE fee of \$405 and the extension of time fee of \$310, for a total of \$715, and are being paid by on-line credit card authorization at the time of EFS filing of this Response and the accompanying RCE.

Authorization is also hereby given, to charge the amount of any additional fee or charge properly payable in connection with the filing and entry of this response and the accompanying RCE, to Deposit Account No. 08-3284 of Intellectual Property/Technology Law.

Respectfully submitted,

/steven j. hultquist/  
Steven J. Hultquist  
Reg. No. 28,021  
Attorney for Applicant(s)

INTELLECTUAL PROPERTY/  
TECHNOLOGY LAW  
Phone: (919) 419-9350  
Fax: (919) 419-9354  
Attorney File No.: 4258-117

**Enclosures:**  
**Request for Continued Examination**

<p>The USPTO is hereby authorized to charge any deficiency or credit any overpayment of fees properly payable for this document to Deposit Account No. 08-3284</p>
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